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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,035	02/09/2001	Tariq Ghayer	BBC-084	8433

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EXAMINER
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JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/780,035

Applicant(s)

GHAYER ET AL.

Examiner

Dong Jiang

Art Unit

1646

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 09 February 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 8 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: 37 and 38.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 4-12, 14-36, 44-46 and 61.  
Claim(s) withdrawn from consideration: 39-43 and 47-60.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No. \_\_\_\_\_  
13. ☒ Other: It is noted that a Notice of Appeal was received on 2/9/05.

  
**BRENDA BRUMBACK**  
SUPERVISORY PATENT EXAMINER  
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Continuation of 11. does NOT place the application in condition for allowance because: the new matter rejection of claims 22-29, 32-36, and 39-46 under 35 U.S.C. 112, first paragraph, would be maintained for the reasons of record set forth in the last Office Action mailed on 09 August 2004. Applicants argue, on page 12 of the response filed on 09 February 2005, that the specification discloses two anti IL-18 single chain antibodies capable of binding IL-18 and comprise two variable regions. Applicants argument has been fully considered, but is not deemed persuasive because the disclosed single chain antibodies comprise one variable region from L chain, and one from H chain. However, the claims, as written, encompass antibodies variable regions both from a L chain, or a H chain, and the specification does not have support for such. "Comprising one variable region from L chain, and one variable region from H chain" is suggested.

The scope of enablement rejection of claims 22-36 and 39-46 under 35 U.S.C. 112, first paragraph would be maintained because it is not predictable that an antibody fragment comprising two variable regions of a L chain, or two variable regions of a H chain would have desired function.

The prior art rejection of claims 4-12, 14-24, 44-46 and 61 under 35 U.S.C. 103(a) as being unpatentable over Kucherlapati et al. (US6,075,181, of record) and Dinarello et al. (J. Leukoc. Biol. 1998, 63:658-664. IDS #A4), would be maintained for the reasons of record set forth in the previous Office Actions. Applicants argue, on pages 15-17 of the response filed on 09 February 2005, that Dinarello does not teach to generate fully human antibodies to hIL-18, and Kucherlapati does not teach to generate fully human antibodies to IL-18, and examiner fails to provide any evidence to support motivation to combine the cited art. Applicants argument has been fully considered, but is not deemed persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, even though neither Kucherlapati nor Dinarello teaches explicitly a human monoclonal antibody to human IL-18, strong suggestion or motivation to make such an antibody can be found based on combination of the references, as indicated by Dinarello that neutralizing anti-IL-18 antibodies are a therapeutic option for specific blockade of human IL-18, which strongly suggests and motivates a person having ordinary skill in the art to seek for anti-IL-18 antibodies suitable for treating human diseases. Further, Kucherlapati provides that a human monoclonal antibody possesses significant advantage in therapeutic application in comparison to the other types of antibodies. As such, it is instantly obvious to a person having ordinary skill in the art to make the presently claimed antibody.